DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 5,2014

B. Braun Medical, Inc.
Angela Caravella
Regulatory Affairs Specialist
901 Marcon Boulevard
ALLENTOWN, PA 18109-9341

Re: K140838
Trade/Device Name: IV Administration Set with Hand Pump
Regulation Number: 880.5440
Regulation Name: Set, Administration, Intravascular
Regulatory Class: II
Product Code: FPA
Dated: October 31, 2014
Received: November 4, 2014

Dear Ms. Caravella:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140838

Device Name
IV Administration Sets with Hand Pump

Indications for Use *(Describe)*

The IV Administration Sets with Hand Pump are intravenous administration sets intended for delivery of fluids from a container into a patient's vascular system. When the hand pump component is activated, the device is intended to deliver only crystalloid and colloid resuscitative fluids. These devices may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness for the solution being infused and duration of therapy.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5. 510(k) SUMMARY K140838

DATE: December 4, 2014

SUBMITTER:
B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341
610-266-0500

Contact: Angela J. Caravella, Regulatory Affairs Specialist
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DEVICE NAME: B. Braun IV Administration Set with Hand Pump

COMMON OR NAME: IV Administration Set with Hand Pump

CLASSIFICATION: Class II, Product Code FPA, 880.5440

PREDICATE DEVICES: Infusomat Space Volumetric Infusion Pump System, B. Braun Medical, Inc., K062700, Class II, FRN, 880.5725

Hospira Infusion Blood Sets, Hospira Inc., K101677, Class II, FPA, 880.5440

Blood Hand Pump Administration Set, Cardinal Health, K050115, Class II, BRZ, 880.5440

DESCRIPTION:

The IV Administration Sets with Hand Pump are single use, disposable, intravenous administration sets with a pressure pump and air guard filter used to deliver fluids from a container into a patient's vascular system rapidly through the use of the pressure pump and/or gravity flow. These sets may be comprised of various generic components which are broadly used throughout the industry such as a bag spike, drip chamber, slide clamp, roller clamp, luer access device, stopcocks, manifolds, tubing, and luer connections. Each of these needleless components have already been cleared through the 510(k) process either individually or as part of a B. Braun IV pump 510(k) which included sets. The unique components to these sets include the manual hand pump and a 15µm filter integrated within the drip chamber to reduce the potential for bubble formation within the set during use. The addition of the hand pressure pump provides the capability for delivering IV fluids more rapidly by compressing the pump by hand.

INTENDED USE:

The IV Administration Sets with Hand Pump are intravenous administration sets intended for delivery of fluids from a container into a patient's vascular system. When the hand pump component is activated, the device is intended to deliver only crystalloid and colloid resuscitative fluids. These devices may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness for the solution being infused and duration of therapy.

SUBSTANTIAL EQUIVALENCE:

Technological Characteristics

Predicate Device - Infusomat Space Volumetric Infusion Pump System (K062700)
The IV Administration Sets with Hand Pump have a similar intended use to the Infusomat Space Sets in that they are indicated for infusion therapy for the delivery of fluids to a patient by gravity or through an increased flow rate through the use of a manually activated hand pump (in the case of the proposed device) or with an electromechanical pump (in the case of the Infusomat Space Infusion Pump). The proposed device contains several of the same materials and components as the Infusomat Space Pump Administration Set predicate device.

Predicate Device - Infusion Blood Sets (K101677)
The IV Administration Sets with Hand Pump have a similar indication for use to the Infusion Blood sets marketed by Hospira for the delivery of fluids from a container to a patient's vascular system. Hospira's sets also allow for the delivery of blood to patients which is outside of the proposed device's indication for use. The hand pump described within Hospira's 510(k) K101677 identifies a cylindrical hand pump with ball check valves, this hand pump design with the ball check features are the same as the hand pump present on the proposed B. Braun IV Administration Sets with Hand Pump.

Predicate Device - Blood Hand Pump Administration Set (K050115)
The IV Administration Sets with Hand Pump have a similar indication for use to the Blood Hand Pump Administration set marketed by Cardinal Health in that they are intended for the delivery of fluids from a container to a patient's vascular system either by gravity or through an increased flow rate through the use of a manually activated hand pump. Additionally, the proposed device and Cardinal's Blood Hand Pump administration set indicates the use of a manually activated hand pump which is also present within the design of the proposed device.

Performance Testing

The following performance standards were utilized in evaluating the functionality of the IV Administration Sets with Hand Pump:

ISO 594-1:1986, "Conical fittings with a 6% (luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements"

ISO 594-2:1998, "Conical fittings with a 6% (luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings"

ISO 8536-4:2010, "Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed"

ISO 10993-1:2009, "Biological evaluation of medical devices - part 1: Evaluation and testing within a risk management process"

ISO 11135-1: 2007, "Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices"

Functional performance testing was completed with the proposed IV Administration Sets with Hand Pump to demonstrate that the sets perform as intended. Results of testing demonstrate that the proposed device performs similarly to the predicate device and can be use safety and effectively according to it's intended use.

Biocompatibility

The materials of construction of a fully assembled IV Administration Set with Hand Pump were tested according to ISO 10993-1:2009.

Biocompatibility test results verify that the IV Administration Sets with Hand Pump materials of construction are safe for their clinical application.

CONCLUSION:

Results of functional performance and biocompatibility testing conducted with the proposed device demonstrate that the IV Administration Sets with Hand Pump are substantially equivalent to the predicate devices and is safe and effective for its intended use.
